Vaccine Declinations Present New Challenges for Public Health

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Over the past century, it would be safe to say that vaccines have saved more lives than any other medical technology. The first vaccine was developed more than 200 years ago to prevent smallpox. Since then, dozens of new vaccines have enabled millions of people to avoid devastating diseases and have prevented untold amounts of human suffering. Public health officials consider increased rates of immunization and the development of new vaccines as keys to safeguarding the health of populations in the future.

Recently, however, a contrary trend has arisen. Reports of risks associated with vaccines have led a growing number of people to decline inoculations, both for themselves and on behalf of their children. These changing attitudes may have profound consequences for public health efforts going forward.

Vaccines and Autism: Is There a Relationship?

Like all pharmaceutical products, vaccines present some level of unavoidable risk. For example, eggs are used in the production of many vaccines, and this can create a hazard for patients with egg allergies. A more far-reaching concern followed publication of an article in *The Lancet* in 1998 suggesting a link between the vaccine for measles, mumps, and rubella (MMR) and the development of autism in children.[1] The link was based on the hypothesized effect of thimerosal, a mercury-based preservative used in that vaccine and in others.

The weight of subsequent scientific opinion against this suggestion has been considerable, with numerous research studies having failed to produce any evidence to confirm it. Moreover, 10 of the 13 authors of the *Lancet* article published a retraction of the suggested vaccine–autism link in 2004.[2] Several of the most prestigious medical organizations in world, including the Institute of Medicine, the World Health Organization, the Food and Drug Administration, and the American Academy of Pediatrics, have explicitly rejected the possibility of a link. Vaccine advocates also note that the use of thimerosal in vaccines was almost entirely discontinued in 2001, yet autism rates have remained unchanged. Nevertheless, concern that vaccines can cause autism remains widespread.

Skeptics of vaccines point out that rates of autism have been rising for several years while at the same time the list of recommended childhood immunizations has continued to grow. Autism often first appears in children who are about the same age at which several recommended vaccines are administered. Many parents find this set of facts too suggestive to ignore, even in the absence of actual scientific support of a causal connection. Some conjecture that if thimerosal is not the culprit, then it is the multiple vaccinations that overload the immune system; however, corroborating data are lacking to support this conclusion as well.

Vaccine Declinations And Community Risk

Concerns about the safety of vaccines have led many parents to decline recommended inoculations for their children. As isolated cases, such declinations pose little risk to the children involved or to the communities in which they live. This is because widespread vaccination can produce a phenomenon known as "herd immunity," which protects everyone, even unvaccinated persons.[3] Most infectious agents require a sufficient number of susceptible hosts to maintain their presence in a population. After a threshold of immunized individuals is achieved, generally in the range of 90%, the infectious agent disappears entirely, and even those without immunity are safe. However, when a sufficient number of members of a community forgo vaccination, the percentage of immunized individuals can fall below the threshold for herd immunity, which gives the infectious organism a chance to re-establish itself.

Children are not the only ones avoiding recommended vaccinations. Studies indicate that many health care workers are declining routine immunization against seasonal influenza.[4] This group includes many hospital-based nurses, who can transmit the disease to susceptible patients, often with lethal consequences. Although these vaccine decliners are clearly not motivated by concerns about developing autism, they often express more general qualms about vaccine risks.

Recent Legal Actions May Embolden Vaccine Decliners

A decision in the fall of 2007 by the National Vaccine Injury Compensation Program, a federal fund that reimburses families for vaccine-related harm, may accelerate the trend toward vaccine declinations.[5] The program awarded compensation to a nine-year-old girl, Hannah Poling, for symptoms of autism related to a rare mitochondrial disorder based on the possibility that her condition had been exacerbated by a series of routine immunizations.

Vaccine skeptics consider this award a concession by the government that vaccines can cause autism, and they have promised to rely on this decision in future cases. However, government officials, including Dr. Julie L. Gerberding, Director of the Centers for Disease Control and Prevention (CDC), have vehemently rejected that interpretation. The fund is structured on a no-fault basis and deliberately resolves scientific uncertainties in favor of claimants. Because the course of Hannah's condition is extremely variable and unpredictable, the program refused to rule out the possibility that her condition was worsened by vaccinations, but it did not affirmatively endorse the conclusion that the vaccines were an underlying cause.

In other legal actions, the U.S. Federal Court of Claims is considering three

sets of claims on behalf of 4,800 parents who allege that vaccines caused their children to become autistic.[6] Decisions are not expected until next year. If the decisions favor the claimants, the implications for childhood vaccination in the U.S. could be considerable.

Mandates as a Policy Response

To encourage widespread vaccination, all states mandate that children receive recommended inoculations as a condition of attending school. However, all of these mandates contain exceptions.[7] Children in every state can avoid vaccination based on clinical contraindications, such as allergies and religious objections. About half of all states also permit people to decline vaccination if they oppose the practice on broader philosophical grounds. Research has found higher rates of unvaccinated children in these states along with higher rates of measles and pertussis, which are vaccine-preventable diseases.[8,9] This finding suggests that increasing rates of vaccine declination are, in fact, jeopardizing herd immunity in some communities.

While public health officials cringe at these trends, solutions are not readily apparent. Stricter mandates for vaccination raise complex legal, ethical, and policy implications.[10] Americans cherish their autonomy, and efforts by government to supersede individual health care choices tend to be viewed with suspicion. As vaccine opponents become increasingly vocal, the subject is taking on increasing emotional intensity. Merck encountered substantial opposition when it launched a vigorous lobbying campaign for state mandates of its vaccine (Gardasil) against virus strains that can cause cervical cancer.[7]

As new vaccines are developed, public resistance seems certain to continue to rise. Will this reluctance to receive vaccinations jeopardize hard-fought gains against infectious diseases? Where will it leave the role of vaccines as an essential public health tool?

The Experts Weigh In

At a symposium held at University of the Sciences in Philadelphia in May 2008, vaccine experts explored these questions from a range of perspectives, and they reached some interesting conclusions.[11] Major medical advances in developing vaccines against a range of conditions lie on the horizon. They represent the fruits of new technologies, particularly genomics. However, although research can uncover new clinical possibilities, success in actually producing vaccines and distributing them to large populations depends as much on social, economic, and political factors as on the underlying science. Vaccines will not reach large numbers of people without mechanisms to fund their development, which can cost hundreds of millions of dollars, systems to distribute them widely and equitably to those in need, and arrangements to reimburse for their cost.

The panelists also agreed that the public must gain a better understanding of the value of this medical technology. Information on risks and benefits should be widely disseminated and clearly presented to counter inaccurate statements about vaccine risks, which exist in abundance on the Internet. In particular, many parents might not appreciate the severity of childhood illnesses, such as polio, that have become distant memories because of vaccination. In other words, they might not be viewing vaccine risks in the context of full vaccine benefits.

To pave the way for the future of vaccines, the panelists saw key roles for many different players. For instance, the federal government should maintain and expand assistance programs for those unable to afford vaccines. The pharmaceutical industry should continue to invest in research and development, even if the payoffs are decades away. Organizations such as the Bill and Melinda Gates Foundation and the Global Alliance for Vaccines and Immunization (GAVI) should maintain and expand their role in funding mechanisms to distribute vaccines, especially in the developing world. Clinicians should remain abreast of medical developments so that they can accurately counsel patients, and parents of patients, on vaccination decisions. All of these roles are essential to the continued success of this primary public health tool.

The Challenge for Policy

The challenge for lawmakers will be to implement policies that harness the skills of all key players to promote vaccine use and development. Mandates will be one tool, but they must be approached cautiously to minimize the fierce opposition that has become increasingly evident. Other elements of this effort should include public and clinician education, increased funding for research into possible vaccine risks, and fair compensation for documented vaccine injuries. The public and the medical community must understand that vaccination benefits the health of entire populations, not just the individuals receiving them. Vaccines can save countless more lives in the future, but components of the entire health care system must be part of the effort to realize this goal.

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